Attorney Docket No. I-6909-1919 US

REMARKS

Upon entry of the above amendment, claims 35-50 will be pending in the present application. Applicants have canceled claims 17-26 and 29-34. Canceled claims 17-26 and 29-34 provide support for new claims 35-50 amended claims 20, 23-25 and 30. Applicants have rewritten the claims as new claims for convenience due to the new amendment process. Applicants have changed the wording of some claims to clarify the subject matter claimed, to correct syntax and to correct typographical errors. Applicants have not raised any issues of new matter.

Applicants have scheduled an Interview with the Examiner on April 24, 2003 to discuss the following.

Objection to the Specification

The specifications stands objected to for the use of various trademarks without generic terminology. Applicants respectfully traverse this objection.

The previous response addressed this issue by capitalizing every trademark and indicating terms as being trademarks. The Examiner has acknowledged that the trademarks are properly capitalized, but the Examiner asserts generic terminology is required.

Applicants again assert that a skilled artisan would understand trademarked products within the context of the specification. Applicants will request further clarification as to the terms objected to.

Applicants respectfully request withdrawal of the objection to the specification.

Claim Objection

Claims 24 and 30 stand objected to. Claim30 is objected to because *Dictyocaulus viviparus* is misspelled. Applicants have canceled claim 30, but have corrected the typographical error in new claim 46.

Applicants have canceled claim 24 and corrected any syntax problems in the new claims.

Applicants respectfully request withdrawal of the objections to claims 24 and 30.

Issue Under 35 U.S.C. §112, First Paragraph

Claim 23 stands rejected under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter outside the scope of enablement. The Examiner asserts that the specification is not enabling for "parts thereof" of SEQ ID NO: 29.

New claim 41 recites an isolated nucleic acid comprising SEQ ID NO: 29 or a nucleic acid that hybridizes to SEQ ID NO: 29 under stringent conditions. Applicants define the term "stringent conditions" on page 7, in the third paragraph. The defined stringent hybridization conditions of 6 x SSC, 68 °C requires that the fragments be of considerable length and homology to hybridize to the described sequences.

A skilled artisan would not understand the limitations as meaning "a nucleic acid consisting of as few as two nucleotides", as suggested by the Examiner. In section 2422.01 of MPEP 8, this shows:

> 2422.01 Definitions of Nucleotide and/or Amino Acids for Purpose of Sequence Rules:
>
> "Nucleotide and/or amino acid sequences as used in 37 CFR 1.821 through 1.825 are interpreted to mean an unbranched sequence of four or more amino acids or an unbranched sequence of ten or more nucleotides."
>
> ". . . the limit of ten or more nucleotides, while lower than certain industry database limits, was established to encompass those nucleotide sequences to which the smallest probe will bind in a stable manner."

(emphasis added).

This means the USPTO itself considers nucleotide sequences of less than 10 nucleotides unfit for stable binding to a probe, very much in agreement with the practical situation. Therefore, the referral in claim 23 to a nucleic acid hybridizing to Seq. Id. no. 29 would **not** comprise nucleotides smaller than 10 bases, based on the USPTO's understanding of the size of the match required for stable hybridizations.

Claim 23 (New claim 46) as interpreted by the definitions found in the specification, clearly is understandable and enabled. "Acceptability of the claim language depends on whether one of ordinary skill in the art would understand what is claimed, in light of the specification." MPEP §2173.05(b).

A skilled artisan would fully understand how to produce an isolated nucleic acid that hybridizes to SEQ ID NO: 29 under stringent conditions, as defined.

Applicants respectfully request withdrawal of the 35 U.S.C. §112, first paragraph rejection.

Issue Under 35 U.S.C. §112, First Paragraph

Claims 24-25 stand rejected under 35 U.S.C. §112, first paragraph as allegedly containing subject matter outside the

scope of enablement. The Examiner asserts that the specification is not enabling for "parts thereof" of the listed SEQ ID numbers.

Applicants have amended claims 24 and 25 to recite "or parts thereof that hybridize to a sequence of the group under stringent conditions . . .." Applicants have discussed this issue at length in the previous paragraphs. Applicants have clearly contemplated and described the aforementioned "parts thereof." "The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation." In re Buchner, 929 F.2d 660, 661, 18 U.S.P.Q.2d 1331, 1332 (Fed. Cir. 1991). Applicants assert that they have met such a burden.

Applicants respectfully request withdrawal of the 35 U.S.C. §112, first paragraph rejection.

Issues Under 35 U.S.C. §112, Second Paragraph

Claims 24-26 stand rejected under 35 U.S.C. §112, second paragraph, for being indefinite. Applicants traverse this rejection.

The Examiner maintains that the term "parts thereof" is indefinite in claims 24-26. As explained above, the term "parts

thereof" is defined in the specification and examples describe a method to obtain such fragments. "Acceptability of the claim language depends on whether one of ordinary skill in the art would understand what is claimed, in light of the specification." MPEP §2173.05(b). Applicants assert that a skilled artisan would understand the claim language as amended.

Claim 26 stands rejected for being indefinite in the use phrase "expressing the cDNA clone obtained according to claim 24 . . .." The Examiner bases this rejection on the rejection of claim 24. Applicants have provided sufficient explanation to assert that claim 24 is definite and fully enabled; thus, logic dictates that claim 26 is also definite and fully enabled.

Applicants respectfully request withdrawal of the 35 U.S.C. §112, second paragraph rejection.

Issue Under 35 U.S.C. §102(b)/103(a)

Claims 17-20 and 29-31 stand rejected under 35 U.S.C. §102(b) for anticipation or, alternatively, under 35 U.S.C. §103(a) for being obvious over de Leeuw et al (Veterinary Parasitology Vol. 39 No. 1-2, 1991, pages 137-147, IDS-10). Claims 17-20 and 29-31 stand rejected under 35 U.S.C. §102(b) for anticipation or, alternatively, under 35 U.S.C. §103(a) for being obvious over Schneider (International Journal of

Parasitology, Vol. 22, No. 7, 1992, pages 933-938). Applicants respectfully submit that patentable distinctions exist between the cited prior art and the present invention.

Distinctions Between the Present Invention and de Leeuw et al. and Schneider

Schneider discloses an amino acid sequence of the Dv3-14 protein, which is available as entry AAB27962, from the NCBI protein database. Using standard sequence alignment software, a homology of around 17% is revealed between Dv3-14 and Dv 17, which is SEQ ID No. 30 of the present application. Therefore, a skilled artisan would not find Dv 17 and Dv3-14 related in any manner.

de Leeuw et al. disclose an immunogenic protein of *Dictyocaulus viviparus* with a molecular weight of 17,000 daltons. The Examiner maintains that Applicants' claim limitations reasonably appear to be the identification of new features of a protein already known in the art. The Examiner acknowledged the 37 C.F.R. §1.132 Declaration by Mr. Hoffman, but found the declaration non-persuasive because of lack of factual evidence.

To prove that distinctions actually exist between the cited prior art and the present invention, Applicants submitted a

Declaration by Mr. Jan Cornelissen, who is a co-author of the publication by de Leeuw. Applicants apologize for referring to Mr. Cornelissen as "Dr." in the previous response, no deceit was contemplated, and it was a clerical error.

As previously discussed, Mr. Hoffman reported that, with respect to de Leeuw et al., he had received a personal communication from Thomas Schneider, an author of the cited reference, reporting that the 17kd protein disclosed by de Leeuw et al. and the 18kd protein disclosed by Schneider both react with the same monoclonal antibody.

Mr. Cornelissen described an experiment, which proved this assertion. Applicants have attached two clearer copies of gels showing the results of the experiments. Applicants will also bring the clearer versions to the Interview of April 24, 2003.

From this actual evidence, Mr. Cornelissen concluded that the 17kd protein of de Leeuw et al. and the 18kd protein of Schneider must be similar proteins and, therefore, must be different from the presently claimed proteins because 18kd protein is different from the instant proteins, as stated above.

Therefore, as Dv 17 is not related to Dv 3-14, which is similar to the de Leeuw protein? A skilled artisan definitely would not find the present invention described within the cited references. More, importantly a skilled artisan would not find the present invention obvious from reading the cited references

because neither reference provides motivation to alter their teachings in any manner.

Applicants respectfully request withdrawal of the 35 U.S.C. §102(b)/§103(a) rejections over the cited prior art.

Conclusion

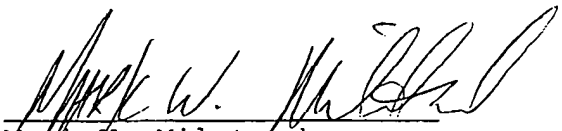
Applicants submit that every issue raised by the outstanding Office Action has been addressed and rebutted. Therefore, the present claims define patentable subject matter and are in condition for allowance.

Applicants believe that the conference will be helpful in advancing the prosecution of this application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2334 for any

additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

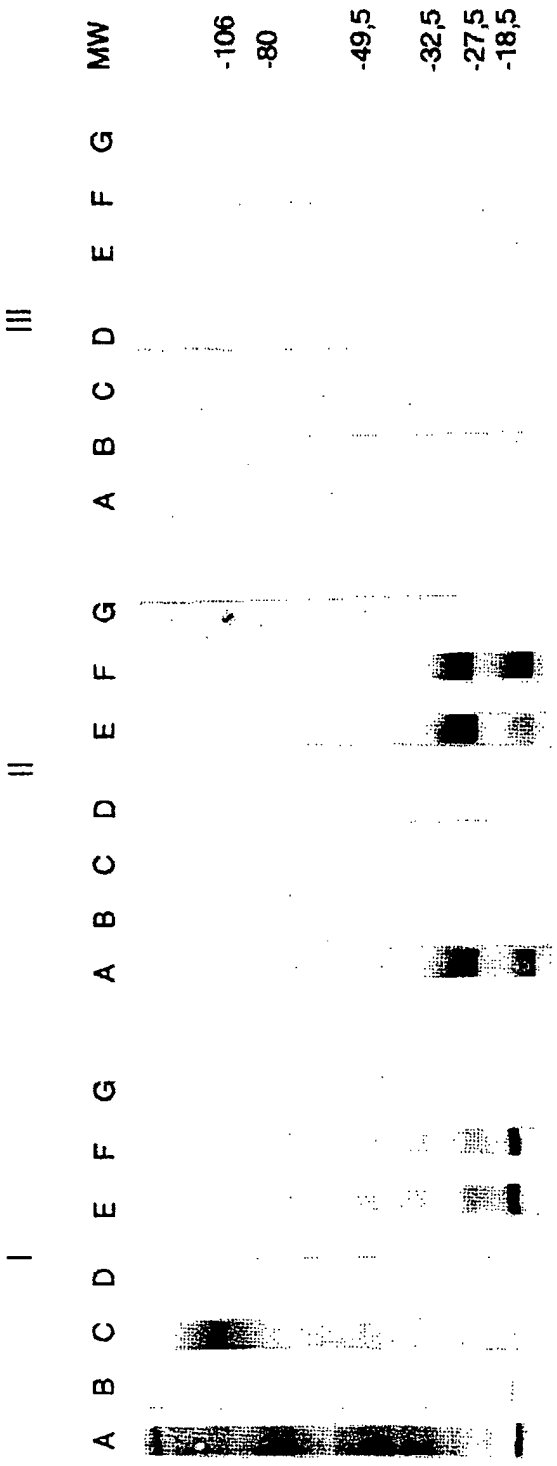


Mark W. Milstead
Registration No. 45,825

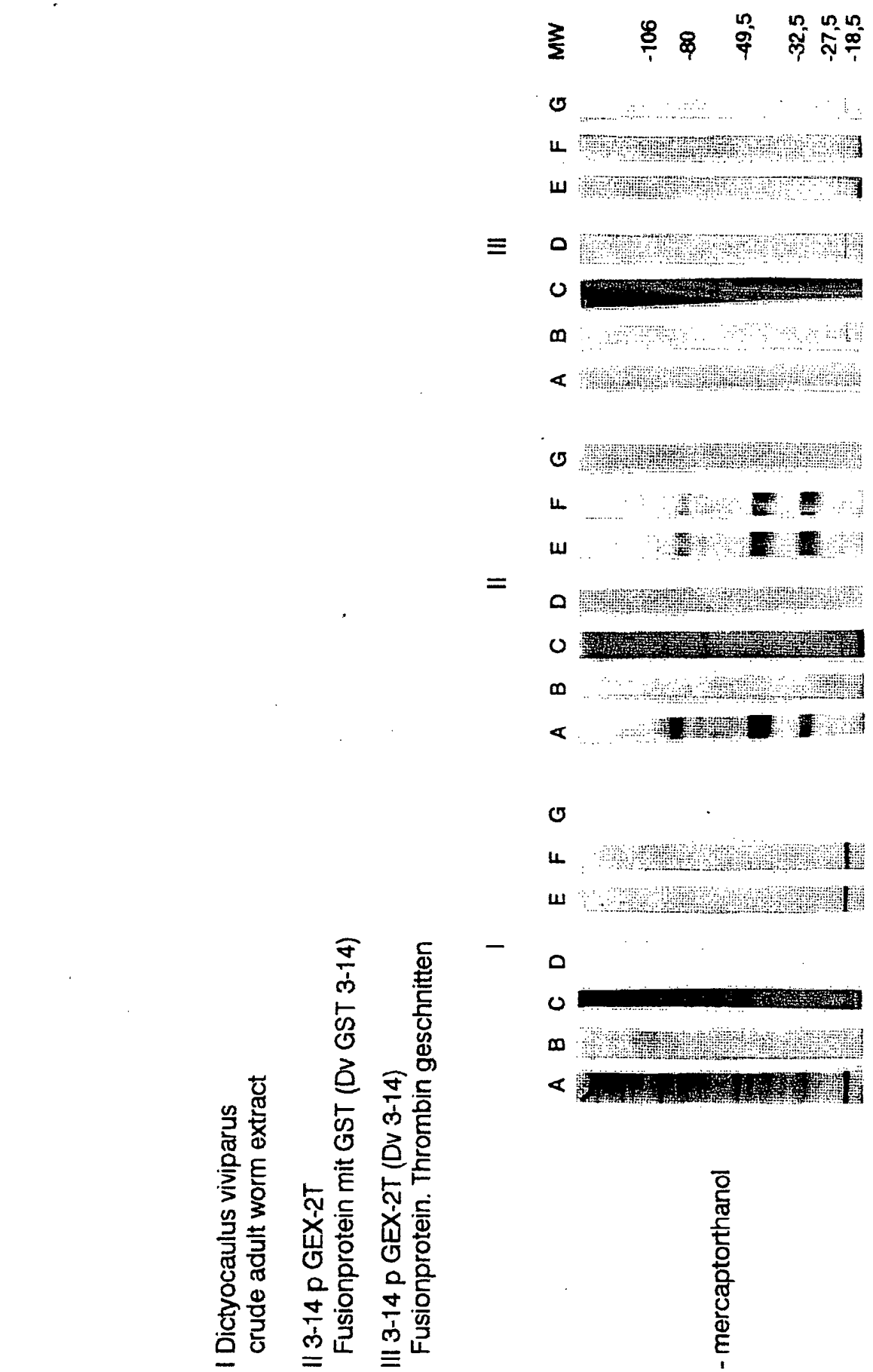
Akzo Nobel Patent Department
Intervet, Inc.
P.O. Box 318
405 State Street
Millsboro, DE 19966
Tel: (302) 934-4395
Fax: (302) 934-4305

Attorney Docket No. I-6909-1919 US
MWM

Enclosure: Copies of Gels



+ mercaptorthanol


I Dictyocaulus viviparus
crude adult worm extract
II 3-14 p GEX-2T
Fusionprotein mit GST (Dv GST 3-14)
III 3-14 p GEX-2T (Dv 3-14)
Fusionprotein. Thrombin geschnitten
- mercaptorthanol
I
II
III
A B C D E F G
A B C D E F G
A B C D E F G
MW
-106
-80
-49,5
-32,5
-27,5
-18,5